

REMARKS

Reconsideration of the application after entry of the amendments in view of the following remarks is requested.

I. ALLOWABLE SUBJECT MATTER

Applicants acknowledge with appreciation the Examiner's indication that claims 99, 100 and 104 are directed to allowable subject matter.

II. REJECTION UNDER 35 U.S.C. §102(B) OVER BRÉARD (USP 5,011,484)

Claims 90-98, 101 and 109-113

The Examiner rejected claims 90-98, 101 and 109-113 under 35 U.S.C. §102(b) over Bréard. The Examiner argued with respect to claims 90-92 that Bréard discloses a method for stabilizing a spinous process relative to another spinous process, where a device is introduced between and conformed to the processes. The Examiner also argues with respect to claims 91, 92, and 98 that the preformed device is made of an elastic or resilient material with a shape memory and has a cantilevered configuration at its lips. With respect to claims 93, 94, and 101 the device has cavities (2, 3, 8) that are fillable with materials. With respect to claims 95-97 and 109-111 the device inherently has shock absorbing and compressible surfaces since it is made of PTFE. Finally with respect to claims 112 and 113, the Examiner argues that **FIGS. 6 and 7** disclose the introduction of a device between spinous processes without alteration of the process.

In summary, Bréard is directed to a surgical implant designed to prevent mutual contact between vertebrae during flexions of the vertebral column. Each "vertebral spine" is housed in a corresponding groove **2** or **3** of the insert. **FIG. 2** illustrates the grooves **2** and **3** which are substantially "U-shaped." The method of Bréard provides that "the device is inserted between the spines of two successive vertebrae. Each 'vertebral spine' is then housed, with a slight amount of lateral play, in a corresponding groove **2** or **3** of the insert" (see Col. 3, Ins. 14-17).

Bréard does not teach that its device be conform to the shape of the spinous process (**claim 90**) as it specifically provides that there is "lateral play." Similarly Bréard does not teach that the device be conformable *in situ* (**claim 91**) because Bréard

specifically provides that lateral play is acceptable. The Examiner assumes merely from the fact that Bréard is manufactured from PTFE that it is therefore "conformable *in situ*." However, Bréard does not teach this. Bréard also does not teach a device that is pre-formed to the shape of at least one spinous process (**claim 92**) as Bréard provides only for substantially U-shaped grooves and makes no mention of pre-forming its device to a spinous process.

Bréard also does not teach a device having a sealable cavity (**claims 93 and 101**) that is fillable with material because the device of Bréard has a "cavity" which is the U-shaped cavity **2**, that can accommodate artificial ligaments or portions of the spine. Bréard does not teach that its cavity can be sealed. Bréard also does not teach a device that has flexible walls defining a sealable cavity capable of being filled with a material (**claim 94**) for the same reasons it does not teach the method of claim 94. Bréard does not teach a device which acts as a shock absorber (**claim 95**), acts as a shock absorber to dampen motion of at least one spinous process (**claim 96**), spreads out forces between the device and any of the spinous processes (**claim 97**), or is comprised of shape memory material (**claim 98**). Nothing in Bréard teaches that its device have any of these qualities that are claimed by Applicants. The Examiner improperly concludes that it is inherent in the Bréard device that it act as a shock absorber which would in effect dampen motion and spread force out. However, Bréard specifically provides that the materials it teaches are chosen because the materials provide a "low friction coefficient" not for any force absorbing quality or shape memory quality. Therefore it cannot be concluded that Bréard teaches a device that acts as a shock absorber.

Bréard teaches that the bone is cut away to accommodate the implant (col. 3, Ins. 17-20). This is also shown in **FIG. 4**. Bréard does not teach a device that is adapted to distract the spinous processes without altering the spinous processes (**claims 112 and 113**).

In order for a reference to be properly applied under 35 U.S.C. § 102(b) each of the elements of Applicants' method claims must be taught by the reference. Bréard fails to teach each of the elements of Applicants' method claims as discussed above. Accordingly, the Examiner is requested to withdraw the rejection of claims 90-98, 101

and 112-113 under 35 U.S.C. §102(b) in view of Bréard. Claims 109-111 have been cancelled therefore the rejection is moot.

III. REJECTION UNDER 35 U.S.C. §102(E) OVER KUSLICH (USP 5,549,679)

Claims 102, 103, 105, 106, and 108

The Examiner rejected claims 102, 103, 105, 106, and 108 under 35 U.S.C. §102(e) over Kuslich. The Examiner has stated that the application of § 102(e) is based on the pre-AIPA version because the application was not filed on or after November 29, 2000. Applicants direct the Examiner's attention to the filing date for this application which is January 8, 2001 and therefore IS on or after November 29, 2000 contrary to the Examiner's assertion.

The Examiner goes on to argue that Kuslich discloses the introduction of a device **146** in the vicinity of or about spinous processes, where the device has a first, loose configuration and a second, rigid configuration; and where the device is not connected to the processes.

One embodiment of Kuslich is directed to a bag that is sausage shaped and not implanted in a disc cavity. Rather, one or more of the bag containers **146** is pre-filled with fill material and positioned against the bone of adjacent vertebrae. The bone may be roughened to a bleeding surface to **hasten** bone growth into the containers. Although Kuslich does not discuss the anatomy in specifics, it is evident from **FIG. 12** that the bag sits adjacent the side of the vertebrae (i.e., adjacent the transverse process) and does not come into contact with the spinous process at all. Nothing in the written description suggests otherwise and no other placement is therefore taught. Further, the object of Kuslich is to provide a mechanism for fusing two vertebrae together by hastening bone growth into the containers (located on the sides of the vertebrae).

Kuslich does not provide a method of introducing a device relative to a spinous process and another spinous process (**claims 102, 103, 105-108**) because the bag taught by Kuslich does not interact with the spinous process at all according to the illustration of **FIG. 12**.

In order for a reference to be properly applied under 35 U.S.C. § 102(e) each of the elements of Applicants' claims must be taught by the reference. Kuslich fails to teach each of the elements of Applicants' claims 102, 103, 105-106 and 108 because, as discussed above, it fails to teach an implant positionable between spinous processes. Accordingly, the Examiner is requested to withdraw the rejection of claims 102, 103, 105, 106, and 108 under 35 U.S.C. §102(e) in view of Kuslich.

IV. REJECTION UNDER 35 U.S.C. §103(A) OVER KUSLICH (USP 5,549,679)

Claims 105 and 107

The Examiner rejected claims 105 and 107 under 35 U.S.C. §103(a) over Kuslich. The Examiner argues that Kuslich discloses the invention substantially as claimed but does not specifically disclose an introduction tool in the method; nor does Kuslich disclose a device with a first temperature in a first configuration and a second temperature in a second configuration.

As discussed above, Kuslich lacks the important step of introducing the device relative to the spinous process required by the independent claim from which claims 105 and 107 depend.

In order to establish a *prima facie* case of obviousness under § 103, three basic criteria must be met according to the MPEP § 706.02(j). "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art...must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure."

For the reasons discussed above, the Examiner has failed to establish a *prima facie* case of obviousness under §103 with respect to claims 105 and 107 and therefore the rejection should be withdrawn.

V. CLAIM OBJECTIONS

The Examiner objected to claims 94 and 113 because of informalities. Applicants have amended the claims to overcome the informalities and therefore requests that the Examiner withdraw the objection to claims 94 and 113.

Applicants also note that claims 91 and 100 were also amended to correct typographical errors in the claims.

CONCLUSION

For the foregoing reasons, the pending claims are patentable over the prior art of record. Applicant respectfully requests that the Examiner allow this application and pass this case to issuance.

FEES

The Commissioner is authorized to charge any underpayment or credit any overpayment to **Deposit Account No. 06-1325** for any matter in connection with this response, including any fee for extension of time, which may be required.

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